

ESTIMATION OF LEAD EXPOSURE FROM WATER SOURCES FOR U.S. CHILDREN

OVERVIEW

Since 1994, the Office of Solid Waste and Emergency Response (OSWER) has recommended the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK model) as a risk assessment tool to support environmental cleanup decisions at lead-contaminated residential sites (U.S. EPA, 1994a, b). The IEUBK model uses data on the presence and behavior of environmental lead to predict a plausible distribution or geometric mean (GM) of blood lead (PbB) for a hypothetical child or population of children.¹ The relative variability of PbB concentrations around the GM is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability.² From this distribution, the IEUBK model estimates the risk (i.e., probability) that a child's or a population of children's PbB concentration will exceed a certain level of concern (U.S. EPA, 1994a; White et al., 1998).

The IEUBK model contains more than 100 input parameters that are initially set to default values. These default values are generally intended to represent national averages or other central tendency values to be used in the absence of site-specific exposure data. Default values are derived from a) empirical data in the open literature that included lead concentrations in exposure media (e.g., concentration of lead in drinking water), b) contact rates such as the soil/dust ingestion, and c) exposure durations (White et al., 1998). In general, information used to support a risk assessment can be characterized as either site-specific environmental media data or community-specific socioeconomic and receptor data. While environmental media data (e.g., air, water, soil) are the most common type of site-specific data entered into the IEUBK model, default values for socioeconomic and receptor data, such as age, body weight, breathing rate or soil ingestion rate, do not typically vary from site to site and are rarely adjusted in the IEUBK model.

The current default value for the *Lead Concentration in Drinking Water* variable in the IEUBK model represents a national central tendency estimate for lead concentration in drinking water (PbW). This value was derived from a combination of PbW data reported by the American Water Works Service Company, Inc. (AWWSC, 1988) and a quantitative analysis performed by Marcus (1989).³ The TRW recommends updating the *Lead Concentration in Drinking Water* variable with a value derived from the U.S. EPA's Second Six-Year Review of National Primary Drinking Water Regulations, or "Six-Year Review" (US EPA, 2010a,b; see Table 1).⁴

The purpose of this document is to review the currently available data on lead in U.S. drinking water, provide the technical basis for updating the *Lead Concentration in Drinking Water* variable, and to

¹The GM represents the central tendency estimate (e.g., mean, 50th percentile) of PbB concentration of children from a hypothetical population (Hogan et al., 1998). It is recognized, however, that a central tendency estimate is equally likely to over- or under-estimate the lead-intake at a contaminated site. Upper confidence limits (UCLs) can be used in the IEUBK model; however, the IEUBK model results could be interpreted as a more conservative estimate of the risk for an elevated blood lead level. See U.S. EPA (1994b) for further information.

²The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate of blood lead concentration. In the IEUBK model, the GSD is intended to reflect only individual blood lead variability, not variability in blood lead concentrations where different individuals are exposed to substantially different media concentrations of lead. The recommended default value for GSD (10) was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

³The AWWSC (1988) performed a survey of the trace element concentrations and characteristics of 10,000 locations throughout the United States (U.S. EPA, 1994a,b).

⁴Due to ongoing analyses of lead in drinking water, the lead dataset was not published as part of the Six-Year Review of National Primary Drinking Water Regulations (U.S. EPA, 2010a). The lead concentration in drinking water dataset obtained from the 1998-2005 National Compliance Monitoring Information Collection Request Dataset (i.e., "Six-Year Review-ICR Dataset"), however, was delivered by U.S. EPA Office of Groundwater and Drinking Water to the TRW for this review. For more information see <http://water.epa.gov/scitech/datait/databases/drink/sdwsifed/howtoaccessdata.cfm>.

recommend an updated default PbW value for use in the IEUBK model. The intended audience for this document is risk assessors who are familiar with using the IEUBK model. For further background information on the use of the IEUBK model in Superfund lead risk assessment, refer to U.S. EPA (1994a) or the Technical Review Workgroup for Lead (TRW) website (<http://epa.gov/superfund/lead/trw.htm>).

Table 1. Comparison of water lead concentrations for use in the IEUBK model.

Source	Constant Water Lead Concentration (µg/L)	Basis for Age-Specific Value
IEUBK Model Default ^a		<u>Methodology</u> Marcus, 1989 Central tendency estimate <u>Water Lead Concentration Data</u> American Water Works Service Company, Inc. (AWWSC, 1988)
Proposed Drinking Water Lead Concentration Value ^b		<u>Methodology</u> Population-weighted, estimate of high end exposure data <u>Water Lead Concentration Data</u> 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)

^a IEUBK model v. 1.1, build 11.

^b Value is intended to be a nationally representative, population-weighted, estimate of high end water lead concentration found in tap water in the U.S. This value does not represent filtered or bottled water consumption. Order of operations: Calculated mean population per sample; observations; all samples multiplied by population weight factor: value * (population / mean population); mean of all samples by location; mean of all means by location.

TECHNICAL ANALYSIS

The TRW identified information on PbW from seven sources (Clayton et al. 1999; Moir et al., 1996; U.S. EPA, 2006a, 2007, 2008, 2010a,c). See Table 2 for an overview of these sources. U.S. EPA (2008, 2010c) and the National Ambient Air Quality Standards (NAAQS) analysis (U.S. EPA, 2006a, 2007) suggest that a constant mean water lead concentration of µg/L is appropriate based on data from two studies of residential water concentrations in U.S. and Canadian homes (Clayton et al., 1999, Moir et al., 1996).

Clayton et al. (1999) based PbW estimates on the results of the National Human Exposure Assessment Survey (NHEXAS) Phase I field studies conducted by the Research Triangle Institute and the Environmental and Occupational Health Sciences Institute. Phase I was conducted in six states in U.S. EPA Region 5 (Ohio, Michigan, Illinois, Indiana, Wisconsin, and Minnesota) between July 1995 and May 1997. The study included a series of questionnaires of personal exposure and onsite physical samples of residential water (both first-draw and flushed).⁵ Clayton et al. (1999) reported the arithmetic mean drinking water concentration for the Region 5 areas as follows: first-draw (n=) water µg/L (% CI: to) and flushed water (n=) µg/L (% CI: to) (see Table 2).

⁵ The NHEXAS study was a federal interagency research effort coordinated by the U.S. EPA Office of Research and Development (ORD). NHEXAS was implemented in three phases: Phase I, scoping studies using probability-based sampling designs; Phase II, a full national exposure survey; and Phase III, a series of focused characterization modules (Pellizzari et al. 1995). Pellizzari et al. (1995) and Clayton et al. (1999) provide further detail the scope and design of Phase I of the NHEXAS study.

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Moir et al. (1996) summarized data on PbW from [REDACTED] single-family homes serviced by municipal water drawn from a lake in Halifax, Nova Scotia, Canada. Two tap water samples over two separate occasions were collected from each location in April and June, 1987. Moir et al. (1996) noted that many of the homes sampled were serviced by lead pipe mains, and that [REDACTED]% and [REDACTED]% of the first-draw and flushed water samples, respectively, from the homes sampled had lead concentrations that exceeded [REDACTED] µg/L. The mean lead concentration for first-draw water was [REDACTED] µg/L (maximum=[REDACTED] µg/L), and for flushed water was [REDACTED] µg/L (maximum=[REDACTED] µg/L) (see Table 2).

Table 2. Comparison of constant lead concentration in drinking water values.

Source	Constant Water Lead Concentration (µg/L)	Basis for Value	
IEUBK Model Default ^a	[REDACTED]	Marcus, 1989	American Water Works Service Company, Inc. (AWWSC, 1988)
Proposed Value ^b	[REDACTED]	U.S. EPA, 2010a Population-weighted, mean estimate of high end exposure data	1998-2005 Six-Year Review-ICR Dataset
Current Analysis	[REDACTED]	Geometric mean	1998-2005 Six-Year Review-ICR Dataset
	[REDACTED]	Population-weighted, mean estimate of high end exposure data	1998-2005 Six-Year Review-ICR Dataset
U.S. EPA, 2010b	[REDACTED]	U.S. EPA, 2008 U.S. EPA, 2007 U.S. EPA, 2006a Clayton et al., 1999 Moir et al., 1996 Geometric mean	1995-1997 NHEXAS Phase I Field Study, U.S. EPA Region 5 ^c 1987 Sampling efforts in Halifax, Nova Scotia, Canada ^d
Clayton et al., 1999	[REDACTED]	Mean first-draw tap water	1995-1997 NHEXAS Phase I Field Study, U.S. EPA Region 5 ^c
	[REDACTED]	Mean flushed tap water	
Moir et al., 1996	[REDACTED]	Mean first-draw tap water	1987 Sampling Efforts in Halifax, Nova Scotia, Canada ^d
	[REDACTED]	Mean flushed tap water	

^a IEUBK model v. 1.1, build 11.

^b Value represents the population-weighted mean estimate of high end exposure data rounded to one significant figure. Value is intended to be a nationally representative water lead concentration found in tap water in the U.S. This value does not represent filtered or bottled water consumption.

^c Values represent [REDACTED] and [REDACTED] samples for first-draw and flushed tap water, respectively. Data were collected in U.S. EPA Region 5 from the six states (Illinois, Indiana, Ohio, Michigan, Minnesota, and Wisconsin) between July 1995-May 1997.

^d Values represent [REDACTED] samples collected from single-family homes in the city of Halifax, Nova Scotia, Canada between April and June 1987.

Amendments to the Safe Drinking Water Act require U.S. EPA to review each National Primary Drinking Water Regulations (NPDWR) every six years. This process, or "Six-Year Review", is a comprehensive assessment of drinking water quality that measures the state of water treatment capabilities, as well as current laboratory analytical methods for the regulated contaminants (U.S. EPA,

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2010b).⁶ As described by U.S. EPA (2010d), during the Six-Year Review process, public water systems must sample homes or other sites with plumbing materials expected to contain lead or copper (i.e., homes connected to water mains by lead pipes, etc.) to detect elevated levels of chemicals (e.g., lead). In addition, drinking water samples must be first draw following a 6-hour stagnation period to allow for corrosion effects to accumulate. The findings of the sampling efforts are reported to the respective Primacy Agency (i.e., states and tribes with primary enforcement authority under the Safe Drinking Water Act) in accordance with 40 CFR 141.90 of the Lead and Copper rule, and additional actions are taken if elevated levels of lead are present (U.S. EPA, 2010d).

Data obtained from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) consisted of [REDACTED] States and Primacy Agencies that comprised of [REDACTED] individual sample monitoring records.⁷ On average, [REDACTED] water suppliers contributed data from each state; the number of suppliers varied from one in Tennessee to [REDACTED] in Texas; on average, [REDACTED] water suppliers voluntarily contributed data. The calculated geometric mean PbW was [REDACTED] µg/L ([REDACTED] % CI= [REDACTED] to [REDACTED] µg/L; see Table 3). In addition, a population-weighted mean PbW of [REDACTED] µg/L ([REDACTED] % CI= [REDACTED] to [REDACTED] µg/L) was calculated based on the population served by each water supplier (see Table 4). The frequency distribution of lead concentration reported by water suppliers is presented in Figures 1 and 2. Estimates for lead concentration were calculated using Microsoft Access. Calculated mean population per sample: [REDACTED] observations. The order of operations was as follows: all samples multiplied by population weight factor: $value * (population / mean population)$, then the mean of all samples by location and finally the mean of all means by location.

Table 3. Summary statistics for mean water lead concentration (µg/L) based on data reported by the U.S. EPA Office of Groundwater and Drinking Water 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)^a

Mean	GSD	Min	Max	N	SEM
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Confidence Limit		MinCL (µg/L)	MaxCL (µg/L)		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		
[REDACTED] %	[REDACTED]	[REDACTED]	[REDACTED]		

Mean: geometric mean water lead concentration; StDev: standard deviation; Min: minimum water lead concentration; Max: maximum water lead concentration; N: number of samples; SEM: standard error of the mean; T: t statistic; MinCL: minimum confidence limit; MaxCL: maximum confidence limit

^aSee U.S. EPA (2010a) for detailed information such as analytical sensitivity, laboratory QA/QC methods, etc.

⁶A national database for receiving and storing public water system data has not been established, and the Six-Year Reviews rely on voluntary reporting of data from the states, territories and tribes (U.S. EPA, 2010b).

⁷The monitoring records were voluntarily obtained from [REDACTED] States and Primacy Agencies (including two Tribal Nations located in U.S. EPA Region 8 and Region 9), and represented approximately [REDACTED] million people nationally. The database did not include data from Kansas, Louisiana, Maryland, Mississippi, New Hampshire, Pennsylvania, and Washington state.

Table 4. Summary statistics for population-weighted mean water lead concentration ($\mu\text{g/L}$) based on data reported by the U.S. EPA Office of Groundwater and Drinking Water 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a)

Mean ^a	StDev	Min	Max	N	S.E.M.
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Confidence Limit	T	MinCL ($\mu\text{g/L}$)	MaxCL ($\mu\text{g/L}$)		
95%	[REDACTED]	[REDACTED]	[REDACTED]		
90%	[REDACTED]	[REDACTED]	[REDACTED]		
80%	[REDACTED]	[REDACTED]	[REDACTED]		
70%	[REDACTED]	[REDACTED]	[REDACTED]		
60%	[REDACTED]	[REDACTED]	[REDACTED]		
50%	[REDACTED]	[REDACTED]	[REDACTED]		
40%	[REDACTED]	[REDACTED]	[REDACTED]		

Mean: population-weighted mean lead concentration; StDev: standard deviation; Min: minimum water lead concentration; Max: maximum water lead concentration; N: number of samples; SEM: standard error of the mean; T: t statistic; MinCL: minimum confidence limit; MaxCL: maximum confidence limit

^aOrder of operations: Calculated mean population per sample: [REDACTED] observations; all samples multiplied by population weight factor: value * (population / mean population); mean of all samples by location; mean of all means by location.

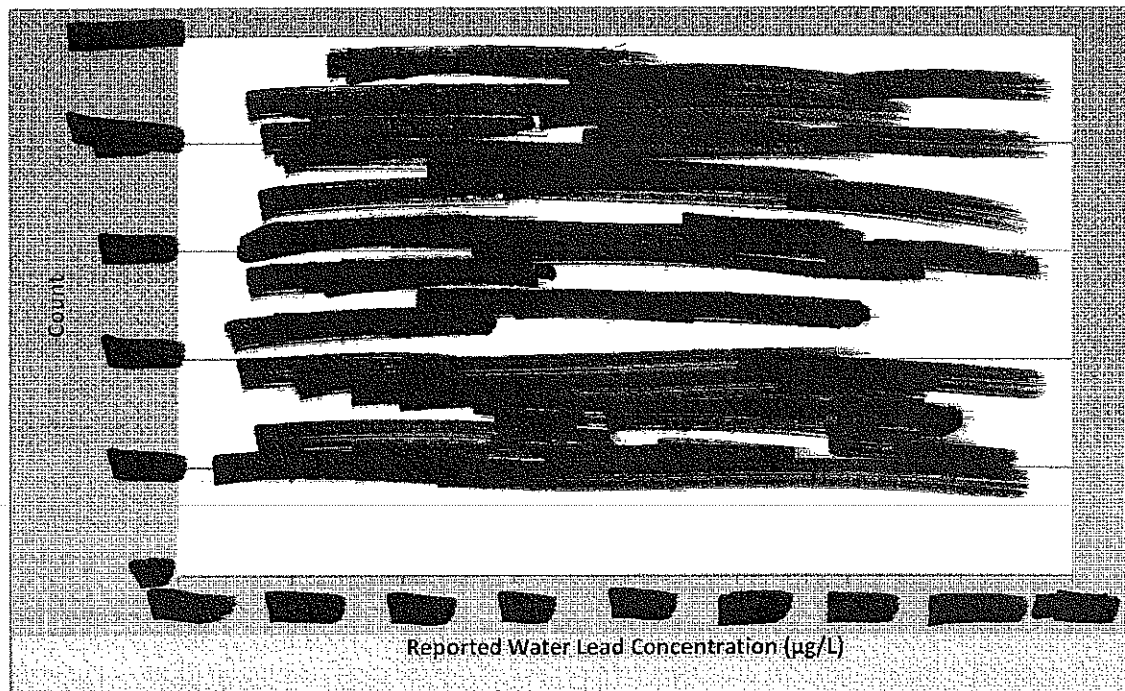


Figure 1. Frequency distribution of mean water lead concentration ($\mu\text{g/L}$) as reported by water suppliers in the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a).

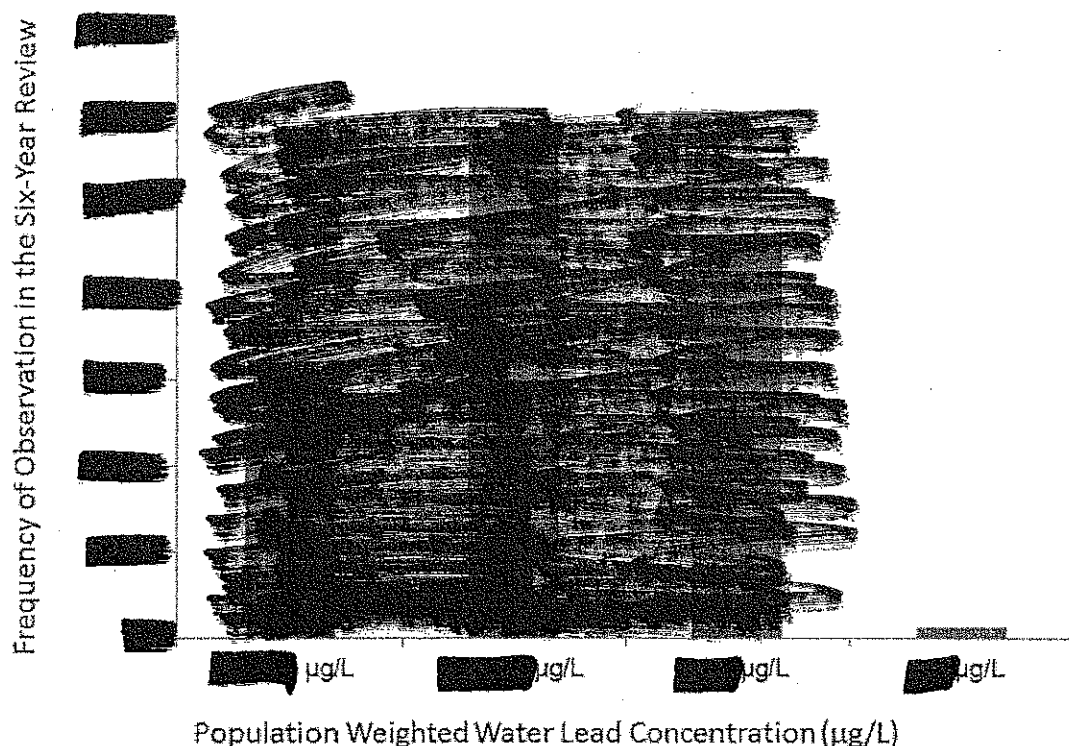


Figure 2. Frequency distribution for the population-weighted water lead concentrations ($\mu\text{g/L}$) as reported by water suppliers in the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a).

UNCERTAINTY

The lead and copper sampling requirements in the Six-Year Review are not designed to assess mean exposure. Rather, the sampling is intended to detect elevated levels of lead if they are occurring in a water system in order to trigger additional actions to reduce lead and copper exposure. These data likely represent the higher levels of lead found in homes served by public water systems throughout the United States. Further, EPA did not conduct quality assurance activities on the data to identify anomalies such as incorrect units, duplicate samples, etc.

RECOMMENDATIONS FOR THE IEUBK MODEL

As described in U.S. EPA (2006a, 2007, 2008, 2010a,c), the range of values (██████ to ██████ $\mu\text{g/L}$) observed in Clayton et al. (1999) and Moir et al. (1996) was considered to be representative of randomly sampled residential water in houses constructed since lead pipe and solder were banned for residential use. The mean water concentration of ██████ $\mu\text{g/L}$ value, however, does not address elevated background exposures encountered in homes with Pb piping and/or very corrosive water.⁸

⁸ If the Clayton et al. (1999) values are entered in the IEUBK model alternate water menu (in place of current and proposed defaults ██████ $\mu\text{g/L}$ and ██████ $\mu\text{g/L}$, respectively), the calculated water lead concentration is ██████ $\mu\text{g/L}$. The current default value (██████ $\mu\text{g/L}$) would be within the confidence limits on the latter estimate (██████ to ██████ $\mu\text{g/L}$). Thus, the Clayton et al. (1999) study does not provide strong support for changing the current default value of ██████ $\mu\text{g/L}$. The data reported in Moir et al. (1996) does not represent a statistically robust sample of the lead concentrations in U.S. drinking water, for the following reasons: (1) the relatively small sample size ($n=██$); (2) limited geographic area of the sample (one area of Nova Scotia); and (3) the potential contribution of lead from lead pipe mains to the water in the sample.

The Six-Year Review is considered as the “largest and most comprehensive contaminant occurrence dataset ever compiled and analyzed by EPA’s Drinking Water Program” (U.S. EPA, 2010b). As such, the TRW considers this dataset as an appropriate source of information to serve as the basis for updating the IEUBK model. Based on the analysis outlined in this document, the TRW recommends updating the default *Lead Concentration in Drinking Water* variable in the IEUBK model using the population-weighted mean estimate derived from the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a). This default value is considered appropriate for all applications of the IEUBK model where current and future residential scenarios are being assessed. The TRW recommends replacing the default with site-specific information if representative site-specific information is available that meet the Data Quality Objectives of the site.⁹ Although site-specific measures will best represent drinking water, there is also a need to run exposure scenarios in the absence of site-specific data (i.e., a default value is necessary). The Superfund Lead-Contaminated Residential Sites Handbook has further information on collecting site-specific water lead concentration data (U.S. EPA, 2003).

IMPACT ON THE IEUBK MODEL PREDICTIONS

Based on using current IEUBK model (v. 1.1, build 11) defaults for all other parameters, implementing the proposed water lead concentration will decrease the geometric mean blood lead concentration for children (████ months of age) from █████ to █████ µg/dL (Table 5). Significant impacts on the predicted blood Pb for any age group, on the probability of the geometric mean exceeding █████ µg/dL, and on PRGs in the soil lead concentration range in the interest for OSRTI were not observed (Table 5).

The proposed value is based on national water concentration averages; however, this value may not necessarily represent subpopulations of children at sites. The IEUBK model will continue to allow (as shown in Figure 3) for input of site-specific water concentration information (e.g., first-draw, flushed, water fountains) that meet the Data Quality Objectives of the site.

⁹ To promote defensible and reproducible site investigations and decision making, while maintaining flexibility needed to respond to different site conditions, U.S. EPA recommends the Data Quality Objectives process (U.S. EPA, 2006b). Data Quality Objectives provide a structured approach to collecting environmental data that will be sufficient to support decision-making.

Table 5. Comparison of the IEUBK model output for selected lead concentrations in drinking water.

Parameter	Age Range (months)										GM	P ₁₀	PRG for % NTE	
													µg/dL (ppm)	µg/dL (ppm)
													µg/dL (ppm)	µg/dL (ppm)
IEUBK Model Default Value (µg/L) ^a														
Lead uptake from water (µg/day)														
Calculated Total Lead Uptake (µg/day)														
Calculated Geometric Mean Blood Lead Concentration (µg/dL)														
Proposed IEUBK model default Value (µg/L) ^b														
Lead uptake from water (µg/day)														
Calculated Total Lead Uptake (µg/day)														
Calculated Geometric Mean Blood Lead Concentration (µg/dL)														

GM: Geometric mean blood lead concentration (µg/dL) for month age range; P₁₀: Probability of the predicted GM blood lead concentration µg/dL; PRG: preliminary remediation goal; NTE: not to exceed

^a IEUBK Model (v. 1.1, build 11)

^b Value based on the analysis of the 1998-2005 Six-Year Review-ICR Dataset (U.S. EPA, 2010a) performed for this review.

^c To better align the CDC recommendation and the risk predictions for lead exposure at Superfund sites, the TRW Lead Committee recommends that the default age range in EPA's tool for determining risk from lead exposure (the Integrated Exposure Uptake Biokinetic Model for Lead in Children; IEUBK model) be modified to match the year age range (months). The values shown are approximate for the month age range.

Figure 3. Proposed IEUBK Model Drinking Water Data Entry Window with the Recommended Drinking Water Lead Concentration Value.

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